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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD, Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, INC. and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 17-5015 (PGS)(DEA) (Filed Electronically)

CONSENT JUDGMENT AND ORDER

WHEREAS, this action for patent infringement ("the Litigation") was brought by Plaintiff Actelion Pharmaceuticals Ltd ("Actelion") against Defendants Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Limited (collectively, "Sun," together with Actelion, "the Parties") for infringement of United States Patent No. 8,598,227 ("the '227 patent");

WHEREAS, Actelion currently markets in the United States, pursuant to New Drug Application No. 022260, epoprostenol sodium for injection, eq. 1.5 mg base/vial and eq. 0.5 mg base/vial, under the trade name Veletri® (the "Veletri Product");

WHEREAS, Actelion's commencement of the Litigation was based on its receipt of notice from Sun that it had filed with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 210473 (the "Sun ANDA") containing a "paragraph IV certification" with respect to the '227 patent and seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of generic versions of epoprostenol sodium for injection, eq. 1.5 mg base/vial and eq. 0.5 mg base/vial (the "Sun Product"), prior to the expiration of the '227 patent;

WHEREAS, on February 15, 2019, the Court issued an interlocutory *Markman* order and memorandum (the "*Markman* order");

WHEREAS, the Parties desire to avoid substantial litigation costs that would otherwise be incurred and conserve the parties' and the Court's resources by resolving the Litigation prior to any final judgment on the merits including appeals therefrom;

WHEREAS, Sun and Actelion have agreed to resolve this litigation, including the avoidance of any appeals from any final judgment, for good and valuable consideration recognized by the parties;

WHEREAS, the Parties hereby have jointly requested that the Court vacate the *Markman* order as part of this consent judgment, and represent that their joint request for vacatur of the *Markman* order was essential to the Parties' coming to a mutually agreeable resolution of the Litigation that foregoes further litigation;

WHEREAS, the Parties have agreed to terminate the pending litigation by the entry of this Judgment and Order; and

WHEREAS, Actelion and Sun now consent to this Judgment and Order.

The Court, upon the consent and request of Actelion and Sun, and upon due consideration and for good cause shown, issues the following Consent Judgment and Dismissal Order.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. Subject matter jurisdiction, personal jurisdiction, and venue are all proper in this Court.

2. The submission of the Sun ANDA to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Sun Product within the United States prior to the expiration of the '227 Patent was a technical act of patent infringement with respect to one or more claims of the '227 Patent under 35 U.S.C. §271(e)(2)(A).

3. The Asserted Claims are valid and enforceable for purposes of this litigation with respect to the manufacture, use, sale, offer for sale, and/or importation of the Sun Product within the United States.

4. Sun and its affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Sun Product until the expiration of the '227 Patent, including any patent term extensions and/or patent term adjustments and during the period of any associated pediatric exclusivity, other than as recognized by the parties.

5. Nothing in this Judgment and Order shall be construed as prohibiting Sun from maintaining and/or (e.g., in the case of a recertification pursuant to 21 C.F.R. § 314.96(d)) filing a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to the Sun ANDA and the '227 Patent.

6. Nothing in this Judgment and Order shall be construed as restricting the FDA from granting final approval of the Sun ANDA.

7. Nothing in this Judgment and Order shall be construed as restricting Sun's ability to commercially manufacture, use, offer for sale, sell, and/or import into the United States the Sun Product before the expiration of the '227 Patent as authorized by Actelion.

8. For the reasons set forth in the parties' Aug. 13, 2019 letter, the *Markman* order, dated February 15, 2019, is vacated. The letter is annexed as Exhibit A to this Order. PGS

9. All affirmative defenses, claims and counterclaims in this action are hereby dismissed without prejudice.

10. Each party shall bear its own fees and costs in connection with this action, including attorneys' fees.

11. The Parties agree that there will be no appeal from this Judgment and Order.

12. This Court shall retain jurisdiction of this action and over the Parties for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED, this 19 day of August, 2019

Peter G. Sheridan
Hon. Peter G. Sheridan, U.S.D.J.

Dated: August 13, 2019

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